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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,757	04/05/2006	David Parkinson	ON/4-33248A	1625

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
WEBB, WALTER E	

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
10/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,757	PARKINSON ET AL.	
	Examiner	Art Unit	
	Walter E. Webb	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-41 are pending and rejected.

Specification

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

The abstract of the disclosure is objected to because there is no mention of the general nature of the epothilone. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 15, 18, 19, 21, and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "refractory tumor" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claims 15, 18, 19, 21, and 24-26 recites the limitation "the tumor" in line 3. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Reilly et al., (US 6,302,838), in view of Williams et al., (Cochrane Reviews 2002).

Applicant's invention is drawn to a method of treating a proliferative disease by administering an epothilone to a warm-blooded animal by daily continuous intravenous

administration lasting 6 to 24 hours (claim 1 and 13). The epothilone can be epothilone B (claim 2). The epothilone is administered at various concentrations (claims 4-7), over various time periods (claims 3 and 8-12), treating different types of tumors (claims 14-38 and 40-41. Applicant also claims a method of treating proliferative disease where epothilone B is in combination another anti-tumor therapeutic (claim 39).

O'Reilly et al. teach a method for treatment of a proliferative disease by administering an epothilone, especially epothilone B to a warm blooded animal (see col. 1, lines 5-8 and 43-47.) The epothilone is useful in treating multidrug resistant and/or Taxol refractory tumors (see col. 1, lines 8-50). The epothilone is administered at various concentrations: 0.1-6 mg/m^2, 0.1-5 mg/m^2, 0.1-3 mg/m^2, 0.1-1.7 mg/m^2, 0.3-18 mg/m^2, 0.3-15 mg/m^2, 0.3-12 mg/m^2, 0.3-7.5 mg/m^2, 0.3-5 mg/m^2, and 1.0-3.0 mg/m^2 (see col. 6, lines 13-23). These dosages are administered daily intravenously during 2-180 min, 2-120 min, 5-30 min, and 10-30 min (see col. 6, lines 24-28). In case of weekly treatment, with rest periods of more than one week, dosing can be 2-10 weeks, and have 3, 4, 6, 8, or more treatment cycles (see col. 6, lines 29-35). In one aspect of their invention the epothilone is in combination with another anti-tumor chemotherapeutic (see col. 6 lines 53-65.) The various tumors treated by their invention include colorectal, head, neck, ovarian, lung, and breast tumors that are refractory to 5-fluorouracil and Taxol (see col. 7, lines 22-60.)

O'Reilly et al. does not teach a daily continuous intravenous administration lasting 6 to 24 hours.

It would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to administer the epothilone if O'Reilly in a daily continuous intravenous administration lasting 6-24 hours, since an adjustment to the time of infusion treatment is simply routine optimization. It is routine optimization to adjust ingredients in a composition to optimize the desired results of the composition.

It would also have been obvious to a person of ordinary skill in the art at the time of applicant's invention to adjust the infusion time of O'Reilly to 6-24 hours since Williams suggests that a compound (paclitaxel or Taxol), which mimics the biological effects and has the same binding site of epothilone, administered at a 24 hour infusion, may be more efficacious compared to a shorter infusion of 3 hours. (see Main Results at pg. 2). A person a having ordinary skill in the art would expect similar success through similar administration of compounds with similar functions and binding sights. "[A] person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1390.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 9:00am-5:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

WW

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER